

**K052489 ACTIHEART**

Sep 27, 2005  
15 days to decision

K052489 · Product code: **GWK** · Neurology  
Source: <https://www.510kdatabase.net/k052489/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Conditioner, Signal, Physiological (GWK)
Date received	Sep 12, 2005
Decision date	Sep 27, 2005
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Respironics, Inc.</b>
Location	Monroeville, PA, US
Contact	ZITA A YURKO
Website	<a href="https://www.respironics.com">https://www.respironics.com</a>
510(k) history	172 submissions · 168 cleared · 1977-2024

Respironics, Inc. is an American medical supply company owned by Philips. It specializes in products that improve respiratory functions and is based in Monroeville, Pennsylvania. The company maintains a strong FDA 510(k) regulatory record spanning from 1977 to 2024. Respironics has received FDA 510(k) clearances from total submissions. The dominant focus is Anesthesiology devices, which represent approximately 90% of all submissions. The latest clearance in 2024 reflects continued regulatory activity. Recent cleared devices include masks, ventilators, and sleep therapy sy...

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